General

Guideline Title

Fecal immunochemical tests compared with guaiac fecal occult blood tests for population-based colorectal cancer screening.

Bibliographic Source(s)

Rabeneck L, Rumble RB, Thompson F, Mills M, Oleschuk C, Whibley AH, Messersmith H, Lewis N, FIT Guidelines Expert Panel. Fecal immunochemical tests compared with guaiac fecal occult blood tests for population-based colorectal cancer screening. Toronto (ON): Cancer Care Ontario (CCO); 2011 Nov 8. Various p. (Evidence-based series; no. 15-8). [44 references]

Guideline Status

This is the current release of the guideline.

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Please visit the Cancer Care Ontario Web site for details on any new evidence that has emerged and implications to the guidelines.

Recommendations

Major Recommendations

- The Fecal Immunochemical Test (FIT) Guidelines Expert Panel recommends that a pilot study be performed to investigate how to implement FIT in the population-based colorectal cancer (CRC) screening program in Ontario. This pilot study should evaluate FIT based on laboratory, field, and economic factors. The laboratory component would evaluate specimen stability under varying conditions and the feasibility of automation. The field component would evaluate kit distribution, labelling of kits, stool sampling, and transportation of completed kits to the laboratory. An economic evaluation would be included.
- Any program implemented should use automated kit labelling (e.g., bar code) and not require a separate requisition for the kit.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Colorectal cancer (CRC)

Guideline Category

Prevention

Screening

Technology Assessment

Clinical Specialty

Family Practice

Gastroenterology

Internal Medicine

Oncology

Preventive Medicine

Intended Users

Hospitals

Physicians

Utilization Management

Guideline Objective(s)

- To evaluate the existing evidence concerning fecal immunochemical test (FIT) to inform the decision on how to replace the current guaiac fecal occult blood test (gFOBT) with a FIT in Ontario's ColonCancerCheck Program
- To evaluate what the performance characteristics (sensitivity, specificity, positivity, and positive predictive value [PPV]) of FIT are when used to detect colorectal cancer (CRC)
- To evaluate what FIT kit factors affect acceptability by users (e.g., card versus vial collection FIT, medication use)
- To evaluate what factors affect specimen stability

Target Population

Men and women at average risk for colorectal cancer (CRC) (i.e., asymptomatic, 50 years of age and older, and with no other risk factors for CRC)

Interventions and Practices Considered

Fecal immunochemical test (FIT)

Major Outcomes Considered

- Performance characteristics including sensitivity, specificity, positivity, and positive predictive value (PPV)

- User acceptability
- Specimen stability

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search

The MEDLINE and EMBASE databases were systematically searched for articles assessing fecal immunochemical test (FIT) screening for colorectal cancer (CRC) published between 1996 and indexed through June 2010. The search strategies used are listed in Appendix D in the original guideline document. Additionally, the websites of a large number of agencies and organizations were also searched for evidence, and a listing of all sources searched and the number of articles ordered and retained appears in Table 2 in the original guideline document. Expert Panel members were also canvassed to ensure that no relevant articles were missed.

In addition to the evidence obtained in this review, the knowledge obtained from the ColonCancerCheck Program will be considered when making recommendations.

Selection Criteria

Eligible sources of information had to meet the following criteria:

1. Published full reports with information on any of performance, usability, or specimen stability factors as listed above
2. Systematic reviews (SRs), randomized controlled trials (RCTs), other prospective study designs, retrospective study designs, and mixed design studies. For the purpose of this paper, systematic reviews including those that are the evidentiary foundation for clinical practice guidelines or health technology assessments, or similar reports were included, provided that they reported in detail (e.g., search methods, selection criteria) on a systematic search and summary of the health care literature for articles on a relevant topic.
3. Reports published in English
4. Reports evaluated at least one FIT kit that is licensed by Health Canada for use in Canada.
5. Reports excluded symptomatic participants.

Number of Source Documents

A total of eleven papers were retained, comprising two systematic reviews, five papers reporting on three randomized controlled trials (RCTs), and papers regarding four other studies.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Quality Assessment of Included Evidence

An assessment of study quality was performed for all the included evidence. For randomized controlled trials (RCTs), no specific instrument was used, but items such as randomization, sample size estimates and power calculation, and funding sources were reported on. The Expert Panel recognizes that, due to the nature of the studies being examined, blinding to the intervention was not always possible, and therefore the lack of blinding was not considered a methodological flaw, nor was lack of a reported period of follow-up.

For the other evidence types, the Quality Assessment of Studies of Diagnostic Accuracy included in Systematic Reviews (QUADAS) tool was used where appropriate. The QUADAS tool is a 14-item questionnaire intended to assess primary studies of diagnostic utility for systematic reviews. The QUADAS instrument can only be used to assess studies of diagnostic utility where one test is compared with another (typically, the gold standard). For diagnostic studies without a comparator, no formal quality assessment was planned.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Development and Internal Review

This Evidence-Based Series (EBS) report was developed by the Fecal Immunochemical Test (FIT) Guidelines Expert Panel. The series is a convenient and up-to-date source of the best available evidence on three clinical issues related to FIT, developed through systematic review, expert consensus, evidence synthesis, and input from practitioners and colorectal cancer (CRC) screening experts. Section 2 in the original guideline document contains the systematic review of the evidence. The draft guidelines derived from the interpretation of that evidence and the expertise of the members of the Panel are detailed in Section 1 in the original guideline document. Sections 1 and 2 were circulated to health care providers, colorectal cancer screening experts and others in Ontario for their feedback. Section 3 in the original guideline document presents the feedback process results and any changes made to the draft document.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Internal Review: Program in Evidence-based Care (PEBC) Director

Prior to the External Review (ER) of this Evidence-Based Series (EBS) draft report, it was submitted for Internal Review on March 9, 2011 to the Director of the PEBC, Dr. Melissa Brouwers, a researcher with expertise in methodological issues. The document was approved, pending changes, by Dr. Brouwers on March 15, 2011.

External Review: Targeted Peer Review (TPR)

Beginning on May 9, 2011, the PEBC Director-approved document was distributed to individuals in Canada with relevant expertise as part of the TPR process. It must be noted that the ER consisted of standardized survey questions that are used for all PEBC guidelines; therefore, some of the included questions regarding the recommendations are not fully relevant to this specific guideline. The survey was completed on June 20, 2011, and the results were analyzed. A total of seven individuals were invited to participate, and a total of seven submitted responses (100% response rate).

Expert Panel Response: Targeted Peer Review

Upon completion of the ER procedure, the Expert Panel reviewed the results of the TPR portion. The EBS was well received, and none of the TPR respondents rated the document as being of low quality or strongly disagreed with the findings. The majority of respondents rated the quality of the document high or highest and agreed with the findings.

External Review: Professional Consultation (PC)

Beginning on May 9, 2011, the PEBC Director-approved document was distributed to individuals within the Province of Ontario with relevant expertise as part of a PC review process. It must be noted that the ER questions in the survey used for all PEBC guidelines are standardized; therefore, some of the included questions regarding the recommendations are not fully relevant to this specific guideline. The survey was completed on June 20, 2011 and the results were analyzed. A total of 262 individuals were invited to participate (a total of 253 received the survey to complete), and a total of 107 submitted responses (42.3% response rate).

Expert Panel Response: Professional Consultation

Upon completion of the ER procedure, the Expert Panel reviewed the results of the PC portion. Generally, the EBS was well-received although some respondents did rate the quality low or lowest and disagreed or strongly disagreed with the findings. However, the majority of the respondents did report the document being of good or high quality and agreed or strongly agreed with the findings. Regarding the comments received, the Expert Panel agrees with the majority of the feedback obtained and will take these comments into consideration moving forward. The Expert Panel agrees with the barriers and enablers identified in the External Review and will take them into consideration moving forward.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are supported by systematic reviews, randomized controlled trials (RCTs), and other studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The performance of fecal immunochemical test (FIT) is superior to the standard guaiac fecal occult blood test (gFOBT) in terms of screening participation rates and the detection of colorectal cancer (CRC) and advanced adenoma (AA).

Potential Harms

False-positive and false-negative results

Qualifying Statements

Qualifying Statements

- The use of fecal immunochemical test (FIT) is associated with greater specimen instability for both time between stool sampling and kit processing (according to the manufacturer's inserts, only three of the examined FITs are stable for ≥7 days, and only two are stable for ≥15

days) and temperature (two studies reported an association between lower temperatures and longer stability). FIT may also be associated with higher positivity rates than is standard guaiac fecal occult blood test (gFOBT). Three studies found higher positivity rates associated with FIT, two of which were statistically significantly higher, while only one of the studies found significantly higher positivity rates associated with gFOBT, in a comparison between the FIT and a high sensitivity gFOBT. Therefore, any screening program considering the use of FIT needs to take these factors into account.

- Care has been taken in the preparation of the information contained in this report. Nonetheless, any person seeking to apply or consult the report is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding the report content or use or application and disclaims any responsibility for its application or use in any way.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Nov 8

Guideline Developer(s)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

Guideline Developer Comment

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

Source(s) of Funding

The Program in Evidence-based Care (PEBC) is a provincial initiative of Cancer Care Ontario. It is supported by the Ontario Ministry of Health and Long-Term Care through Cancer Care Ontario. All work produced by the PEBC is editorially independent from its funding source.

Guideline Committee

Fecal Immunochemical Test (FIT) Guidelines Expert Panel

Composition of Group That Authored the Guideline

Panel Members: Linda Rabeneck, MD, MPH, FRCPC (*Chair*), Vice President, Prevention and Cancer Control Cancer Care Ontario, Toronto, ON; R. Bryan Rumble, MSc, Research Coordinator, Cancer Care Ontario's Program in Evidence-based Care, Department of Oncology, McMaster University, Hamilton, ON; Frank Thompson, MD, Midland, ON; Michael Mills, MD, CCFP, FCFP, Regional Primary Care Lead, Hamilton Niagara Haldimand Brant LHIN, Cancer Care Ontario, Juravinski Regional Cancer Centre, Hamilton, ON; Curtis Oleschuk, MD, FCACB, Clinical Biochemist, Department of Clinical Biochemistry and Genetics, Diagnostic Services of Manitoba, Winnipeg, MB; Alexandra Whibley, BSc(Hons), Project Coordinator, Cancer Care Ontario, Toronto, ON; Hans Messersmith, MPH, Assistant Director, Quality and Methods, Program in Evidence-Based Care, Cancer Care Ontario, McMaster University, Hamilton, ON; Nancy Lewis, PhD, Senior Policy and Planning Officer, Cancer Care Ontario, Toronto, ON

Financial Disclosures/Conflicts of Interest

None declared

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

Availability of Companion Documents

The following are available:

- Fecal immunochemical tests compared with guaiac fecal occult blood tests for population-based colorectal cancer screening. Summary. Toronto (ON): Cancer Care Ontario (CCO); 2011 Nov 8. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario (CCO) Web site .
- Program in Evidence-Based Care (PEBC) handbook. Toronto (ON): Cancer Care Ontario (CCO); 2012. 14 p. Electronic copies: Available in PDF from the CCO Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on September 6, 2013.

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